REMARKS

The present response is intended to be fully responsive to all points of objection and/or rejection raised by the Examiner and is believed to place the application in condition for allowance. Favorable reconsideration and allowance of the application is respectfully requested.

Applicants assert that the present invention is new, non-obvious and useful. Prompt consideration and allowance of the claims is respectfully requested.

Status of Claims

Claims 1 – 63 are pending in the application. Claims 1 - 62 have been rejected.

Claim 63 is allowed.

Claims 1-7, 9-12, 14, 19, 22-28, 31-34, 36-49, 52-53 and 59 have been amended.

Claims 8, 54-58 have not been changed.

Claims 13, 15-18, 20-21, 29-30, 35, 46, 48, 50-51, 60-63 have been canceled without prejudice or disclaimer. In making this cancellation without prejudice, Applicants reserve all rights in these claims to file divisional and/or continuation patent applications.

Applicants respectfully assert that the amendments to the claims add no new matter. The above amendments are made to improve the form of the claims for U.S. practice.

CLAIM OBJECTIONS

Examiner objected to claims 18, 25-28, 35-36 and 41-61 due to informalities.

Examiner objected to claim 18 because "said one or more structures" lacks antecedent basis. This claim has been cancelled because of lack of relevancy to the invention.

Examiner objected to claim 25 because it is unclear how this subject matter relates to the subject matter of claim 1. Claim 25 has been amended to clarify in which step of the method adult stature is estimated.

Examiner objected to claim 26 because "said analysis" is a method step. Claims 26 has been amended to be clearer by relating to the step of "determining at least one effect of said structure on said at least one signal" in claim 19.

Examiner objected to claims 31-32 because "said analysis" is a method step. Claims 31-32 have been amended to be clearer by relating to the step of "estimating the age of said structure" in claim 1.

Examiner objected to claims 27 and 28 because "said analysis" has already been claimed as "from said ossification-actuated skeletal structure" in claim 1, and it was unclear to the examiner how it would now be "from a scanning acoustic signal transmitter" or in the case of claim 28, "from a multi-beam acoustic signal transmitter". Claims 27 and 28 have been amended to be clearer, and now they relate to the transmitter and the structure of claim 1.

Examiner objected to claim 35 because he believes this claim should depend from claim 32 and not claim 26. Claim 35 has been cancelled because of irrelevancy to the amended claims of the invention.

Examiner objected to claim 36 because "said acoustic information" lacks antecedent basis, and furthermore, it is unclear how this claim relates to claim 1. Claim 36 has been amended, and instead of "wherein said acoustic information is constructed", now the method of claim 1 further comprises a step of "transferring said age into a database of bone age measurements".

Examiner objected to claims 41-48 and 60-61 because it is unclear how these further method steps relate to the measurement of bone age as claimed in the independent claim. Claims 41-48 have been amended to relate to the method of claim 1, and claims 60-61 have been cancelled.

Examiner objected to claim 49 because of incompleteness. Claim 49 has been amended and the functions performed by the computer in claim 49 are focused and accurate.

CLAIM REJECTIONS

35 U.S.C. § 102 Rejections

In the Office Action, the Examiner rejected claims 1, 12-15, 17-21, 24, 27-31 and 33-34 under 35 U.S.C. § 102(e), as being anticipated by Sarvazyan et al. (US Patent No. 6,468,215) – herein referred to as Sarvazyan. Applicants respectfully traverse this rejection in view of the remarks that follow.

Sarvazyan discloses a method of assessment of **bone** conditions by acquirement of unilateral sequential ultrasonic measurements **along the trajectory over the surface of an examined bone**. The method utilizes measurements of a set of ultrasonic parameters from a plurality of ultrasonic transducers moved **along the tested bone surface**. **To eliminate the influence of soft tissues on the measured parameters**, the thickness of soft tissue layer over the examined area of bone is measured by pulse-echo ultrasonic channels incorporated in the transducers. Based on the ultrasound parameters and their combinations, quantitative evaluation of bone mineralization (ossification) status, structure and cortical thickness is made.

Figure 1 illustrates the apparatus of Sarvazyan:

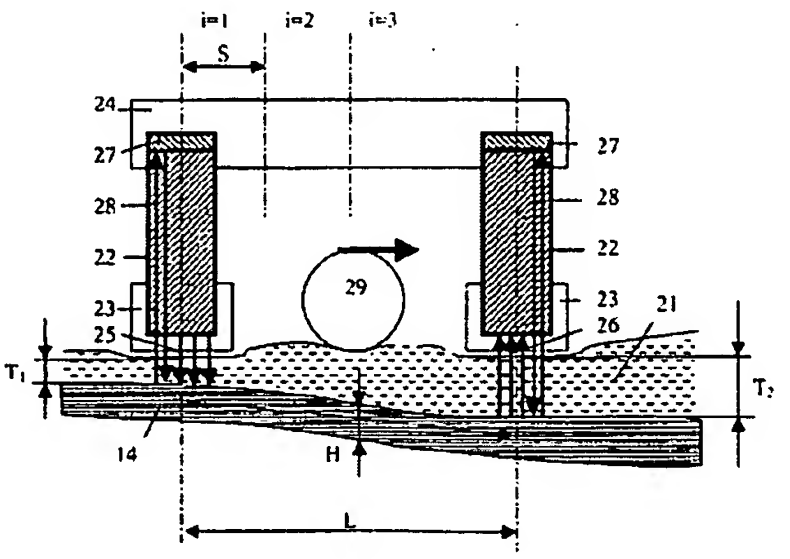


Figure 1

The amended claim 1 of the present invention (referred to hereinafter as Tsoref) claims the following:

"A method for measuring bone age comprising:

(a) providing an apparatus for estimating bone age by at least one acoustic signal in an ossification-actuated skeletal structure, comprising:

(I) an acoustic transmitter and an acoustic receiver positioned ***facing each other*** *so that said structure is positioned between them;* ***said structure comprises at least two bones****; said transmitter is adapted for transmitting said at least one signal* ***to cross said structure transversely****; said receiver is adapted for receiving said at least one signal transmitted by said transmitter;*

(II) an electronic moveable gantry for adjusting the position of said acoustic transmitter and said acoustic receiver in relation to said structure;

(III) a computer system enabled to perform one or more functions of:
controlling said signal transmitted by said transmitter; and
estimating said bone age responsive to said received signal by at least one bone age calculation formula.

(b) transmitting said at least one signal into said structure by said transmitter;

(c) receiving said transmitted at least one signal by said receiver;

(d) analyzing said at least one signal and determining at least one effect of said structure on said at least one signal; and

(e) estimating the age of said structure by using said determined effect and said formula."

Figure 2 illustrates the apparatus of Tsoref:

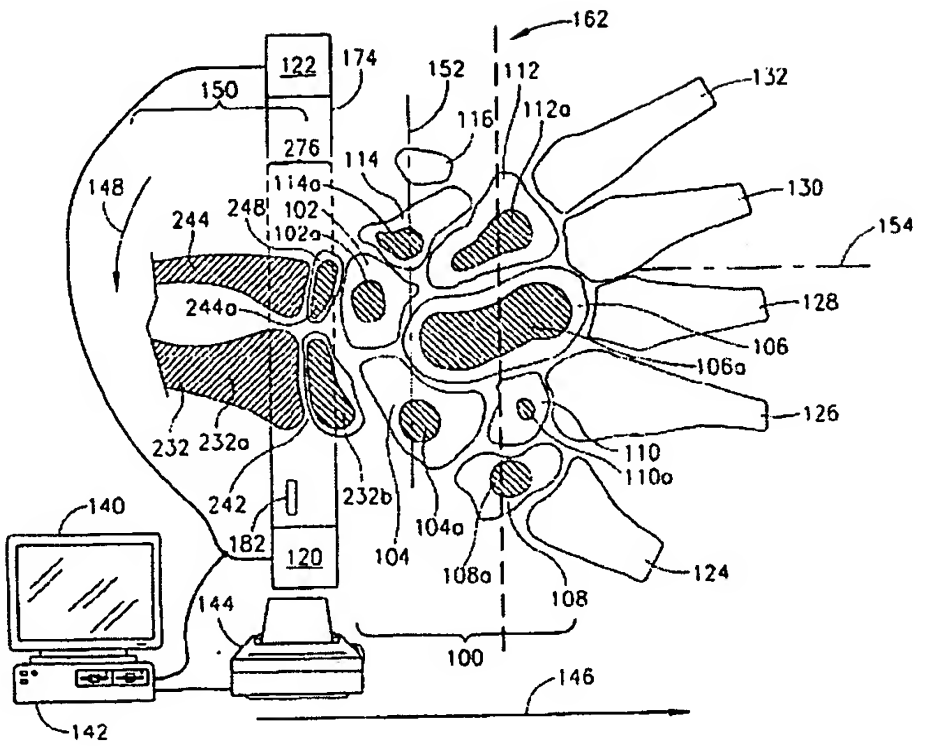


Figure 2

The applicant submits that there are critical distinctions between Servazyan and Tsoref:

(1) In the apparatus and method of Tsoref, the acoustic transmitter and the acoustic receiver are positioned **facing each other,** so that the ossification-actuated skeletal structure is positioned between them (claims 1 and 49, Tsoref). In complete contrast, in the apparatus and method of Sarvazyan the transmitter and the acoustic receiver are positioned **one beside other,** along the tested bone surface (*seen* in Figure 2, Sarvazyan).

(2) In the apparatus and method of Tsoref, the measured acoustic signal is one that **crosses the structure (the bone of the wrist) transversely** (Claims 1 and 49). In the apparatus and method of Sarvazyan, the measured acoustic signal is one that enters the structure, advances along the structure, and

exits the structure from **the same side** that it entered the structure, and not in the other side of the structure, as in Tsoref (*seen* in Figure 2, Sarvazyan).

(3) In the apparatus and method of Tsoref, the acoustic signal that is measured by the receiver crosses "***at least two bones***" (claims 1 and 49). The apparatus and method of Tsoref monitors ossification areas such as the wrist that include a few bone ossification areas and also soft tissue areas (claims 2 and 4-12, Tsoref), such as the distal end of the radius, the distal end of the wrist, the epiphyseal growth plates and etc. In complete contrast, Sarvazyan discloses a method of assessment of **one bone** condition (e.g. claim 1, Sarvazyan). In the specification and claims of Sarvazyan it is always written "bone" and not "bones".

(4) In the apparatus and method of Tsoref, the soft tissue influences the signal, and is part of the measurement (claims 2 and 4-11, Tsoref). In complete contrast, Sarvazyan **eliminates** the influence of soft tissues on the measured parameters (claim 2, Sarvazyan).

In view of the foregoing amendments and the remarks above, the invention of Tsoref comprises novel elements which are not known in the art. Therefore, it is our opinion that the rejected claims 1, 12-15, 17-21, 24, 27-31 and 33-34 under 35 U.S.C. § 102(e), are not anticipated by Sarvazyan, and hence allowable.

In the Office Action, the Examiner rejected claims 49-52 under 35 U.S.C. § 102(b), as being anticipated by Brandenburger (US patent No. 4,926,870).

The amended claim 49 of the Tsoref is the following:

" *An apparatus for estimating bone age by at least one acoustic signal in an ossification-actuated skeletal structure, comprising:*

(a) an acoustic transmitter and an acoustic receiver positioned facing each other so that said structure is positioned between them; said structure comprises ***at***

***least two bones**; said transmitter is adapted for transmitting said signal to cross said structure transversely; said receiver is adapted for receiving said at least one signal transmitted by said transmitter;*

(b) an electronic moveable gantry for adjusting the position of said acoustic transmitter and said acoustic receiver in relation to said structure;

(c) a computer system enabled to perform one or more functions of:

controlling said signal transmitted by said transmitter; and

*estimating said bone age responsive to said received signal by at least one **bone age calculation formula**."*

The device of Branderburger is adapted for estimation of bone strength by an ultrasound analysis. The device of Tsoref and the device of Brandenburger are distinct in the following:

1. The device of Tsoref is adapted for estimation of bone age by transmitting acoustic signal through an ossification-actuated skeletal structure which comprises **at least two bones** (Claims 1 and 40, Tsoref). The device of Brandenburger is adapted for estimation of bone strength for Osteoporosis. This estimation is performed in areas which comprise **one bone**, and not two bones or more. For example, in the specification of Brandenburger it is said: "The patella is desirable as a bone measurement site for a number of reasons..." (*see* column 11, line 30, Brandenburger).

2. The device of Tsoref comprises a computer system enabled to perform bone age estimation by a special **bone age calculation formula** (claim 1, Tsoref). The device of Brandenburger **does not** comprise this formula (because it is intended to calculate other parameters for other purposes). As discussed below, currently existing devices for bone strength estimation by ultrasonic techniques avoid performing the measurements in ossification-actuated

skeletal structures which also comprise at least two bones (especially in children).

The formula that calculates the bone age, as appears in the specification of Tsoref (Page 5, paragraph 86):

BA = (SOS-1566)/27.9 for females [Eqs. 1]

BA =(SOS -1655)/15.6 for males [Eqs. 2]

where speed of sound (SOS) is in units of m/s and bone age (BA) is given in years. These formulae, for instance, are valid for an age range of 4-18 years.

In view of the foregoing amendments and the remarks above, the invention of Tsoref comprises novel elements which are not disclosed by Brandenburger. Therefore, it is our opinion that the rejected claims 49-52 under 35 U.S.C. § 102(e), are not anticipated by Brandenburger, and hence allowable.

35 U.S.C. § 103 Rejections

In the Office Action, the Examiner rejected claims 2-11, 22-23, 26, 36-38, 40, 46 and 62 under 35 U.S.C. § 103(a), as being unpatentable over Sarvazyan alone. Applicants respectfully traverse this rejection in view of the remarks that follow.

It is our opinion that it would not be obvious to one of skill in the art to estimate bone age in the area wrist in the way it is performed by the apparatus of Tsoref.

As disclosed in pages 14-15 of the present document, the apparatus and the method of Tsoref for bone age estimation are absolutely different from the apparatus and the method of Sarvazyan. The method of Sarvazyan is for measurement of ultrasonic signal's passage in areas that are **different** from the bones of the wrist (which comprise for example the distal end of the radius, the distal end of the wrist, the epiphyseal growth plates). The apparatus of Sarvazyan is intended to be applied to **one bone**, to perform ultrasonic measurements along a **trajectory** of the bone (and not

transversely to the structure, as in Tsoref) (claim 1, Sarvazyan). The apparatus of Tsoref uniquely measures ultrasonic signal passage in primary and secondary ossification centers (such as the bones of the wrist) which have a high correlation with bone age (claim 7 and 9, Tsoref). No other apparatus known in the art performs similar techniques for bone age estimation. The applicant wishes to indicate that measurement of ultrasonic signal that passes directly through ossification centers of the ulna and the radius **sequentially** (as in Tsoref), and ultrasonic signal that passes in a specific long bone, are two totally different techniques for bone age estimation. It is not obvious to one of skill in the art to estimate bone age by ultrasonic techniques specifically in the bones of the wrist.

The applicant has performed a series of scientific trials to evaluate the performance of proposed bone age apparatus. The results showed that the device of Tsoref is capable of assessing skeletal maturity, with high correlation with the G&P method (Greulich and Pyle - the most commonly used system in the United States for this purpose). These results have been published in scientific papers such as: *Mentzel H.J. and Vilser C. et al. "Assessment of skeletal age at the wrist in children with a new ultrasound device", Pediatric Radiology, Volume 35, Pages: 429-433, April, 2005.*

In view of the presented above, the invention of Tsoref comprises elements which are not obvious to one of skill in the art in the view of Sarvazyan alone. Therefore, it is our opinion that the rejected claims 2-11, 22-23, 26, 36-38, 40, 46 and 62 under 35 U.S.C. § 103(a) are allowable.

In the Office Action, the Examiner rejected claims 16, 32, 35 and 39 under 35 U.S.C. § 103(a), as being unpatentable over Sarvazyan in the view Kaufman et al. (US patent No. 5,458,130). Applicants respectfully traverse this rejection in view of the remarks that follow.

Claims 16 and 35 have been cancelled by the applicant.

Claim 32 discloses the formula presented in page 16 of this document. This formula is a linear equation for bone age estimation by using speed of sound, and has

no connection with Neural Networks. Regarding claim 39, the applicant considers that this claim is completely unrelated related to Kaufman. Therefore, it is our opinion that the rejected claims 16, 32, 35 and 39 under 35 U.S.C. § 103(a) are allowable.

In the Office Action, the Examiner rejected claims 25, 41-45 and 47-48 under 35 U.S.C. § 103(a), as being unpatentable over Sarvazyan in the view of the Applicant's admitted prior art. Applicants respectfully traverse this rejection in view of the remarks that follow.

As presented above, the present invention discloses innovative method for bone age estimation which is totally different from the method of Sarvazyan, and the other known in the art techniques (such as Greulich and Pyle). Therefore, it is our opinion that the rejected claims 25, 41-45 and 47-48 under 35 U.S.C. § 103(a) are allowable.

In the Office Action, the Examiner rejected claims 53-56 under 35 U.S.C. § 103(a), as being unpatentable over Brandenburger in the view of Sarvazyan. Applicants respectfully traverse this rejection in view of the remarks that follow.

The apparatus of Brandenburger is adapted for estimation of bone strength by an ultrasound analysis to detect osteoporosis. The Examiner claims that if a person skilled in the art combines the apparatus of Brandenburger with the invention of Sarvazyan, the present invention would be obvious. The applicant contends that this is not the case and presents the following arguments.

The apparatus of Brandenburger detects osteoporosis by ultrasonic techniques. This apparatus is relevant to the field of quantitative ultrasound (QUS) for the measurement of bone strength as first reported by Langton et al. in 1984. Since 1984, the use of QUS has expanded vastly, and it has been widely used for research and clinical purposes. It is known that in QUS **one specific bone** is measured. It is also known that in QUS measurement in children, it is recommended to avoid performing measurements of grown plate and ossification areas. It can be seen in pages 310-312 the following book: *Quantitative Ultrasound: assessment of osteoporosis and bone*

status, Informa HealthCare, 1999, the author of the book says that the best positioning of the device is in "the medial aspect of the heel". He also mentions that "in children, **the growth plate (epiphysis)** is located posteriorly to this region..., thus the location of this calcaneal region of interest is **crucial** for reproducible BUA measurements in children...". Thus, the author ***recommends avoiding the growth plate area***, while in the present invention, the growth plate area is measured on purpose to estimate bone age (the growth plate is located in the wrist which is the region of interest in the apparatus of Tsoref). Therefore, it is not obvious to apply a QUS device specifically to ossification areas (such as the bones of the wrist) for purposes other than measuring bone strength, such as bone age estimation, since it contradicts the conventional opinion of the prior art, at the time of filing.

Brandenburger and Sarvazyan do not teach measurement of ossification areas in at least **two bones**, and specifically in the bones of the wrist (crossing the wrist transversely, as presented in Figure 2). Both Brandenburger and Sarvazyan perform their measurements **on one bone**. The acoustic signal of the present invention crosses a bone, and then passes through a soft tissue, and than again crosses a bone. That is totally different from crossing only one bone, because if the influence of the soft tissue on the signal (ultrasonic signal is slower in soft tissues than in bones). Therefore, the present invention discloses a novel method and apparatus which are not known in the prior art, and are not obvious to one skilled in the art.

In view of the presented above, the invention of Tsoref comprises elements which are not obvious to one of skill in the art in the view of Sarvazyan combined with Branderbuger. Therefore, it is our opinion that the rejected claims 53-56 under 35 U.S.C. § 103(a) are allowable.

In the Office Action, the Examiner rejected claims 57-58 under 35 U.S.C. § 103(a), as being unpatentable over Brandenburger in the view of Kaufman. Applicants respectfully traverse this rejection in view of the remarks that follow.

As presented in the previous page the present document, the present invention is not obvious in the light of Brandenburger alone, because it is adapted for measurement of specific area of the body which are not obvious to a person skilled in the art. When combining the Neural Networks techniques of Kaufman with the apparatus of Brandenburger, the present invention is still not obvious to a person skilled in the art for the reasons mentioned above. Therefore, it is our opinion that the rejected claims 57-58 under 35 U.S.C. § 103(a) are allowable.

In the Office Action, the Examiner rejected claims 59-61 under 35 U.S.C. § 103(a), as being unpatentable over Brandenburger in the view of Sarvazyan. Applicants respectfully traverse this rejection in view of the remarks that follow.

Claims 60-61 have been cancelled.

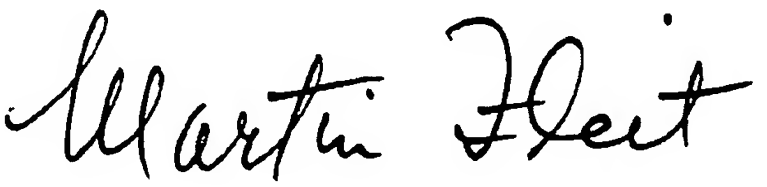
As present above, the present in invention is not obvious in the light of Brandenburger in the view of Sarvazyan. Therefore, it is our opinion that the rejected claim 59 under 35 U.S.C. § 103(a) is allowable.

In the light of the presented above arguments, it is our opinion that the method and apparatus of the present invention comprise novel and not obvious elements, and are therefore patentable.

In light of the foregoing amendments and remarks, this application should be in condition for allowance, and early passage of this case to issue is respectfully requested. If there are any questions regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

It is respectfully requested that, if necessary to effect a timely response, this paper be considered as a Petition for an Extension of Time, time sufficient, to effect a timely response, and shortages in this or other fees, be charged, or any overpayment in fees be credited, to the Deposit Account of the undersigned, Account No. 500601 (Docket no.7057-X09-096)

Respectfully submitted,



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